

REMARKS

This paper is a response to the outstanding final office action of April 26, 2006. This paper is substantively identical to the previously submitted amendment/response. Claims 1-3, 6-7 and 89-93 are pending in the present application. Claims 4-5 and 8-88 were all previously cancelled without prejudice. No amendment has been made in the instant application, inasmuch as Applicants respectfully submit that the art cited by the Examiner has been misinterpreted and misapplied in making out a rejection under 35 U.S.C. §103. It is respectfully submitted that the previously amended claims meet the requirements of 35 U.S.C. and are clearly patentable over the art of record.

A review of the present claims in comparison to the disclosures cited against the instant application evidences that the presently claimed compositions are clearly patentable over the disclosures of Cohn, US patent no. 4, 826,945 ("Cohn"), in view of Newkirk, US patent no. 4,094,797 ("Newkirk") and Sakai, US patent no. 4,081,494 ("Sakai").

The Examiner has rejected pending claims 1-3, 6, 7 and 89-93 under 35 U.S.C. §103 as being invalid over Cohn, in view of Newkirk and Sakai for the reasons which have been stated in the office action. Essentially, it is the Examiner's view that Cohn teach multi-block polymers comprising diblocks of poly(hydroxycarboxylic acid) and poly(oxyalkylene) ethers, but not endcaps on such polymers. The Examiner cites Newkirk for teaching the endcapping of polyoxyalkylene compounds with an aliphatic monocarboxylic acid. Improved resistance to oxidation is disclosed. The Examiner relies on the teachings of Sakai for disclosure of trifunctional agents to achieve crosslinking. From these combined disclosures the Examiner considers that it would have been obvious or one of ordinary skill in the art to endcap the terminal polyoxyalkylene block of the polymers of Cohn as taught by Newkirk to achieve the beneficial effect of improved resistance to oxidation of Newkirk. Applicants respectfully traverse the Examiner's rejection. Applicants note that the Examiner, in making his rejection,

insists that Cohn teaches *diblocks*. Applicants respectfully traverse the Examiner's rejection.

The present invention is directed to novel crosslinked diblock polymers comprising AB diblocks which are crosslinked, where A is a polyester block and B is a polyether (poly)oxyalkylene block which is end-capped with a non-reactive group. Polymeric compositions according to the present invention exhibit unexpected activity as storage stable compositions of definitive structure, the size or molecular weight of which can be fairly easily controlled and modified. Compositions may vary greatly in viscosity and in form with contemplated compositions being used primarily as viscous solutions and gels, although numerous other forms are clearly contemplated by the present invention. The compositions, because they are based upon diblocks which are end-capped, generally have molecular weights which are significantly reduced in comparison to triblock/multiblocks, for example, those which are disclosed in Cohn. The advantage of the present polymers is that they can be used to produce biodegradable or bioerodible viscous formulations which exhibit varying viscosities for purposes of providing unique polymers, in particular, post-surgical polymers which can be delivered to a site within a patient's body to prevent adhesion formation. This can be done despite the crosslinked structure of exemplary polymers of the present invention. It is the combination of stability as well as the ability to readily control viscosity of the polymeric materials (at low or high viscosities, as defined by the length of the A or B block and the amount of crosslinking which occurs) which makes these polymers patentably distinguishable over the polymers disclosed by Cohn, in view of Newkirk. Compositions according to the present invention are particularly attractive for use in medical applications, and in particular, as barriers for preventing or reducing adhesion and in delivering drugs and other bioactives to patients. The relatively low viscosity in certain applications, gives advantageous structural features which enable polymers according to the present invention to be delivered in applications where films are contraindicated. Numerous other uses for the present compositions are also contemplated by the invention.

The Examiner has rejected original claims 1-3 and 6-7 as being invalid under 35 U.S.C. §103 as being unpatentable over Cohn, in view of Newkirk and Sakai. Applicants respectfully

traverse the Examiner's rejection.

Cohn, contrary to the Examiner's reading, does not disclose or suggest polymers which render the present invention unpatentable. In particular, Cohn is directed to certain chain-extended ABA triblock polymers which are unrelated to the present invention. As indicated, the present invention is directed to diblock polymers, not triblock polymers. In Cohn, ABA triblock polymers are produced wherein the two A blocks are made by building polymeric chains off of a central B block comprised of polyethylene oxide or another polyoxyalkylene block. The A blocks are then chain-extended to produce the Cohn disclosed compositions. There is no disclosure or hint that diblocks according to the present invention are desirable or even should be made or that end-capping is even desirable. Indeed, Cohn is silent on the desirability of the use of diblocks as used in the present invention.

There is some confusion on the teachings of Cohn as it relates to a discussion of *diblocks*, which has surfaced in the Examiner's application of Cohn to the present application. Although Cohn discloses, as one aspect of his invention (see abstract and column 3, lines 3-18), multiblock polymers which may contain *putative* polyester/polyalkylene diblocks in a complex *multiblock* system (because in certain polymeric compositions a or b may be zero), these polymers are completely unlike the present polymers and would not motivate the routineer to produce end-capped crosslinked diblock polymers according to the present invention.

The attention of the Examiner to the production of the multiblock polymers which are described/disclosed above is drawn to column 5, lines 3-40. That description in Cohn sets forth the method of production of the polymer which the Examiner relies on for the teaching of diblocks according to the present invention. A review of that section of Cohn evidences that Cohn produces the multiblock *putative* diblock polymers by first taking an ABA triblock polymeric compositions (see column 5, lines 25-28) and rearranging the triblock polymer through a transesterification/lactoyl scission reaction which is catalyzed by Sb_2O_3 catalyst in the presence

of elevated heat to vastly increase the molecular weight of the original ABA triblock. This reaction produces the transesterified multiblock polymer which the Examiner relies upon to teach the present diblock polymers. Note that because the lactoyl scission mechanism of Cohn is not specific to a particular lactic acid monomer within a polymer chain that can vary greatly in the number of monomeric units of lactic acid, the final product of Cohn *may* contain minor amounts of diblock segments in an overall polymer structure which contains triblock and multiblock segments. Note however, the Cohn polymers because of the way they are made from ABA triblocks, do not contain end-capped diblocks (which would be incompatible with the method of production) and do not contain crosslinking agents (because the heat reaction forces a series of transesterification/scissions reactions which dramatically increase molecular weight of the rearranged ABA triblocks. Thus, both the description of the multiblock polymers of Cohn, as well as the method of producing those polymers, is completely inconsistent with the presently claimed invention.

In the present invention, end-capped diblock polymers are first produced and then the end-capped diblocked polymer is crosslinked to produce crosslinked diblock polymers according to the present invention. The polymers according to the present invention are controlled with respect to content and molecular weight and provide advantages not known from the prior art. The polymers of the present invention are completely unlike the polymers of Cohn, and do not contain the transesterified ABA or AA'B- type multiblock polymers, which are, by necessity, present in Cohn as the primary component(s).

It is respectfully submitted that Cohn does not teach diblock polymers, but rather generally teaches chain triblock ABA-type polymers or multi-block AA'B-type multiblock polymers, which are produced by transesterifying the original ABA triblock polymers. It is noted that in each instance where Cohn discloses a polymer, that polymer is *always* based upon a triblock polymer which may be a chain-extended triblock polymer. There is simply no place in the specification of Cohn the Examiner can point to as disclosing a diblock polymer and in particular, an end-capped polymer,

similar to that used in the present invention. There is clearly no teaching in the specification of Cohn which teaches crosslinked diblock polymers according to the present invention. Note that where a and b are greater than 0, the resulting polymer is an AA'BAA'-type multiblock polymer which is produced by transesterification of the basic ABA triblock polymer disclosed therein. Those composition are clearly not the present invention. In instances where AB or A'B diblocks are present in a polymeric composition which also (by necessity from the reaction conditions) by necessity contains numerous types of blocks including AA'B or AA'BAA' multiblocks, those polymeric compositions are clearly not the present invention. Notwithstanding those teachings and the method of production taught by Cohn, whatever polymeric composition is produced in Cohn, such polymer is clearly not an end-capped diblock polymer and that composition certainly not crosslinked. Indeed, the basic rationale behind the Cohn polymerization reaction in the presence of heat is to increase the molecular weight of the polymer without crosslinking. Cohn clearly does not disclose or suggest the present compositions.

The specification of Cohn (at column 9, line 35) speaks to the use of the chain-extended triblock polymers disclosed therein for use in fabrics, wherein more than one type of polymeric filament may be used. All of the examples of Cohn refer to the preparation of triblock polymers. In sum, contrary to the Examiner's contention, there is simply nothing in Cohn which suggests that diblock polymeric compositions according to the present invention may be made or advantageously used as in the present invention. Consequently, it is respectfully submitted that there is absolutely no disclosure or suggestion which can be gleaned from Cohn which either discloses or suggests endcapped diblock polymers which are crosslinked as in the present invention.

Note that Cohn discloses a number of uses of the polymers disclosed therein at column 3, lines 64-68 and column 4, lines 12, which suggest that the polymers will have high molecular weight and a structural integrity reflective of the use of such polymers in surgical devices such as sutures, ligatures, needles, surgical clips, staples, wound coverings (films), screws, etc. which clearly emphasize and teach one of ordinary skill the importance of high molecular weight

polymers (and the polymerization reaction in the presence of heat to increase the molecular weight of the polymers). As has been indicated, one of the advantages of the compositions of the present invention is that because of the end-capped diblock configuration (in contrast to the triblock configuration of Cohn) the molecular weight of the polymers of the present invention may be more readily controlled to a lower molecular weight with structural integrity and reduced viscosity because the present compositions avoid the use of an additional polymeric A block within the structure of the polymer. The diblock polymers according to the present invention may be used to advantageously produce materials which have relatively low viscosities which find use in applications such as in post-surgical applications after minimally invasive surgical methods (e.g., laparoscopy). There is simply nothing in Cohn which discloses or suggests the advantages or the desirability of the present compositions. If anything, Cohn emphasizes the need for the structural integrity of polymers and a high molecular weight polymer produced from ABA triblocks. In such respects, Cohn actually *teaches away* from the present invention.

The Examiner further cites Newkirk against the present invention. Nothing in Newkirk can be used to embellish the disclosure of Cohn to render the present invention obvious. Newkirk discloses oxidation stable fiber lubricants which are based on the polymeric structure set forth in columns 3 and 4 of Newkirk. These are endcapped polyoxyalkylene polymers. While Newkirk may disclose the advantages of end-capping certain multiblock polyoxyalkylene polymers which are unrelated to those of in the instant invention, certainly Newkirk in no way motivates the basic polymeric structure of the present invention, the disclosure or suggestion of which is absent in Cohn. In combining Cohn and Newkirk, one is still left with a basic polymeric structure which is not a polymer based upon AB blocks according to the present invention. Even assuming *arguendo*, that Newkirk does motivate the end-capping of the polymers of Cohn¹, the resulting compositions would not bring to mind the present polymeric

¹ Applicants concede this point only for the sake of argument-it is clear that Newkirk does not motivate end-capping where oxidation is not a critical concern and its protection not a critical requirement-because this is not taught in Cohn. Also, end-capping would result in limiting the molecular weight of the Cohn polymers- something which is

compositions because of the clear distinction between the polymeric compositions of the present inventions and the polymers which are disclosed in Cohn (which are *triblocks or are always produced from triblocks*). By combining Cohn and Newkirk, assuming that it was even reasonable to do so, would result in *at best* an end-capped triblock polymeric composition or an end-capped AA'BAA'-type polymeric composition² or some amalgam thereof, neither of which would relate to the present invention or render the present invention unpatentable.

Turning to Sakai, this reference does nothing to cure the clear deficiencies of Cohn and Newkirk in failing to suggest the present invention. Sakai is cited for teaching the general principal of crosslinking polymers. Sakai does not disclose or suggest end-capped diblocks or the crosslinking of end-capped diblocks. In combination with Cohn and Newkirk, Sakai adds nothing to the combination of references which completely fails to render the present invention obvious. The object of Sakai is directed to providing a method to produce thermoplastic aromatic polyester elastomer having improved transparency for use in the manufacture of plastic tubing. The mere teaching of the fact that certain compositions disclosed therein may be crosslinked adds nothing to the disclosures of Cohn and Newkirk in failing to render the present invention obvious.

In order to render an invention obvious based upon the combined teachings of cited references, there must be *motivation* by one of ordinary skill in the art to produce the claimed invention from the combined disclosures cited. Here there is no motivation. Cohn does not in any way teach or suggest the compositions according to the present invention for the reasons which have been detailed above. Newkirk endcaps unrelated polyoxyalkylene fiber lubricant polymers because of oxidation problems not relevant to the problem the present compositions sought to solve. Sakai, also cited, is directed to polymeric compositions which may be used to

undesirable based upon the uses disclosed for the Cohn polymers.

2 Following Cohn in transesterifying the ABA triblock polymers, one would more likely be left with a polymer which could not be easily characterized or identified- even if it were end-capped.

produce flexible tubing. While it is not clear to Applicants just what those combinations *do motivate*, it is absolutely clear the combined teachings of the art do not teach or suggest the presently claimed compositions.

Consequently, for the reasons which are presented hereinabove, it is respectfully submitted that the claimed invention is in compliance with the requirements of 35 U.S.C. Applicants respectfully assert that the claims set forth in the amendment to the application of the present invention are now in condition for allowance and such action is earnestly solicited.

Applicants have neither cancelled 1 nor added any claim. No fee is believed to be due for the presentation of this amendment. Small entity status pertains to this application. A notice of appeal is enclosed as is the accompanying fee. The Commissioner is authorized to charge any deficiency in fee or to credit any overpayment to deposit account 04-0838.

Respectfully submitted,

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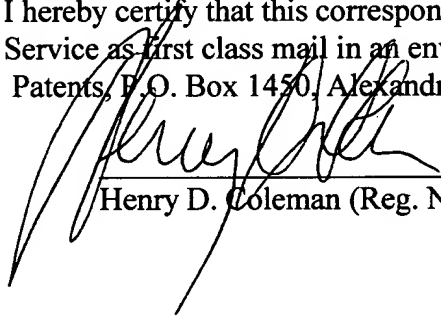
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July 26, 2006
Dated: ~~February 13, 2006~~

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